PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Brian J. Brown, Michael L. Davis**
Application No.:	**09/934178**
Filed:	**August 21, 2001**
For:	**Improved Longitudinally Flexible Expandable Stent**
Examiner:	**Paul Prebilic**
Group Art Unit:	**3774**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2N-5605-US05

APPEAL BRIEF

This is an Appeal Brief for the above-identified application. A Notice of Appeal was filed in this case on December 9, 2009, along with a Pre-Appeal Conference Request and Pre-Appeal Brief. A Panel Decision from the Pre-Appeal Brief Review was mailed on March 2, 2010.

The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

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(i) Real Party in Interest

This Application is owned by Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.), One Scimed Place, Maple Grove, Minnesota 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

For the purpose of complying with the requirements of 37 C.F.R. § 41.37(c)(1)(ii), the following chain of priority is set forth below, followed by a listing and explanation of related Appeals and/or Interferences.

The Immediate Application is a continuation of Application No. 08/511,076. Application No. 08/511,076 is a continuation-in-part of Application No. 08/396,569.

Application No. 08/396,569, in-turn, has the following descendants (in no particular order):

09/878,596; 10/705,273; 10/817,508; 10/918,971; 11/519,552; 09/599,674; 08/511,076; 09/122,431; 09/666,866; 09/934,178; 10/194,854; 10/728,513; 10/800,572; 09/197,278; 09/957,983; 10/063,179; 10/996,088; 11/781,031; and 12/205,394.

The Immediate Application was amended pursuant to a Preliminary Amendment filed on August 21, 2001 in an effort to interfere with US 6,106,548 to Roubin et al. The Preliminary Amendment of August 21, 2001 is herein attached as Appendix D. The claims of the Preliminary Amendment have subsequently been amended and an interference has **not** been declared.

An Appeal to the BPAI was taken in Application No. 10/800,572 with the filing of a Notice of Appeal on July 28, 2008, and an Appeal Brief on August 29, 2008. No decision was rendered by the Board as prosecution was re-opened on November 28, 2008. Then, on October 16, 2009, a Notice of Appeal was filed and an Appeal Brief submitted on December 16, 2009. Currently, no response or other communication has been sent by the Office in response to the Appeal Brief.

An Appeal to the BPAI was taken in Application No. 10/705,273 with the filing of a Notice of Appeal and Appeal Brief on July 10, 2008. No decision was rendered by the Board as an RCE was filed on October 29, 2008, thereby disposing of the Appeal. Subsequently, on March 03, 2010 an Appeal to the BPAI was taken with the filing of a Notice of Appeal. No Appeal Brief has yet been submitted.

An Appeal to the BPAI was taken in Application No. 09/666,866 with the filing of a Notice of Appeal on August 23, 2004, and an Appeal Brief on November 23, 2004. No decision was rendered by the Board as prosecution was re-opened on February 4, 2005.

An Appeal to the BPAI was taken in Application No. 10/063,179 with the filing of a Notice of Appeal on June 25, 2008, and an Appeal Brief on July 10, 2008. The Examiner's Answer was mailed on March 03, 2009 and a Reply Brief was filed on May 04, 2009. No Decision has yet been rendered by the BPAI.

In addition, with respect to Application No. 10/063,179, OrbusNeich Medical Inc. commenced litigation in the eastern District of Virginia (Docket number 2:09CV115-HCM/JEB) on March 16, 2009 against Boston Scientific Corporation. Neither the instant application, nor Application No. 10/063,179, was mentioned in the complaint. The litigation pertains, *inter alia*, to Boston Scientific's Liberté™ stent. The case was transferred to the District of Massachusetts on June 08, 2009 and given a Docket number of 1:09cv10962. As of March 30, 2010, no decision had been rendered by the Court.

An Appeal to the BPAI was taken in Application No. 08/511,076 with the filing of a Notice of Appeal on April 07, 1997, and an Appeal Brief on May 29, 1997. The Board issued a decision on September 25, 2001, a copy of which is included herewith in the Related Proceedings Appendix.

(iii) Status of Claims

Claims 9, 10, 13-22, 24-26, and 28-30 are pending in this application, stand finally rejected, and are the subject of this appeal. Claims 1-8, 11, 12, 23, and 27 have been canceled.

(iv) Status of Amendments

No amendments have been filed subsequent to the final rejection of August 10, 2009.

A review of the timeline is as follows: A Final Office Action was mailed on August 10, 2009; Applicants submitted a Notice of Appeal filed concurrently with a Request for Pre-Appeal Conference and Pre-Appeal Brief on December 09, 2009; a Panel Decision maintaining the rejections was mailed on March 02, 2010. This Appeal Brief is submitted subsequent to the Panel Decision.

(v) Summary of Claimed Subject Matter

Reference is made herein to page and line numbers of the Application as-filed on August 21, 2001. A copy of the Application as-filed is included herewith in the Evidence Appendix and labeled "Appendix A."[1] In addition, reference is made to the Amended Drawings and Amended Specification as submitted on May 20, 2003, which is labeled "Appendix B."[2] Finally, reference is made to the Amended Specification as submitted on September 05, 2006, which is labeled "Appendix C." Appendix A will be referred to herein as "app. A"; Appendices B and C will referred to as "app. B" and "app. C", respectively.

Amended Drawings 3 and 4[3] are included below, for reference.

Independent claim 9 recites a stent having a plurality of cells 24 (e.g., fig. 4, app. B; replacement paragraphs, page 3, app. B) and a plurality of segments 16 (e.g., fig. 4, app. A; page 2, lines 27-28, app. A) which form a tubular body, the tubular body having a circumference. The tubular body comprises a plurality of annular elements 16 (e.g., fig. 4, app. A). Each annular element has a compressed state and an uncompressed state (e.g., fig. 2 and fig. 3, app. A, respectively). Each annular element 16 is formed in a generally serpentine wave pattern (e.g., fig. 4, app. A). Each annular element 16 contains alternating valley portions 19a (e.g., fig. 4, app. A) and peak portions 19b (replacement paragraph, page 2, app. C). The tubular body further comprises a plurality of connecting members 20 (e.g., fig. 4, app. A; page 4, lines 16-17, app. A) connecting adjacent annular elements 16 to form a plurality of cells 24 which are bounded at a first end by a portion of one annular element 16, at a second end by a portion of another annular element and two connecting members 20 which extend between the one annular element 16 and the other annular element (e.g., fig. 3, app. B). The first end is offset in a circumferential direction from the second end relative to the circumference of the body (e.g., fig. 4, app. B). Each annular element 16 has a structure, the structure of a first annular element 16a of the stent provides the stent with less compression resistance than provided by the structure of

[1] Note that the page numbering of the Application has been retained and does not correspond to the page numbering of this Brief.
[2] Page numbers of Appendix B are those shown on the upper left hand corner of the page and do not correspond to the page numbering of this Brief.
[3] It is noted that these drawings have been cleaned up to remove the word "proposed" from the figures as submitted in app. B in order to prevent confusion. The drawings have not been altered in any material way.

a second annular element 16 of the stent (e.g., page 5, lines 5-8, app. A; fig. 4, app. A). The valley portions 19a of the first annular element 16a have the same shape as the peak portions 19b of the first annular element 16a (e.g., fig. 4, app. A). The first annular element 16a is located at an end of the stent (e.g., page 5, lines 5-8, app. A; fig. 4, app. A). Each cell 24 of the stent is bounded at a first end by a portion of one annular element 16, at a second end by a portion of another annular element 16, and by two connecting members 20 which extend between the one annular element and the other annular element (e.g., fig. 4, app. B).

Fig. 3

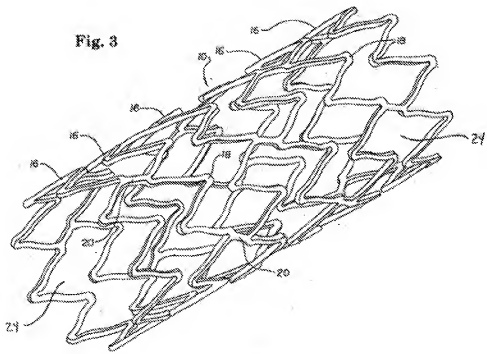
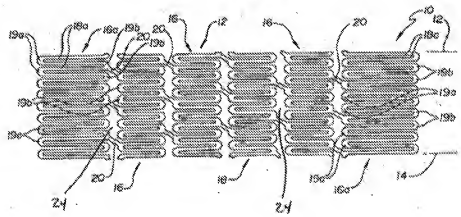


Fig. 4



Independent claim 16 recites a stent comprising an expandable framework defining a tubular body having a plurality of cells 24 (e.g., fig. 4, app. B; replacement paragraphs, page 3, app. B). The framework comprises a plurality of annular elements 16 (e.g., fig. 4, app. B). Each annular element 16 is formed in a generally serpentine wave pattern having a plurality of peaks 19b and troughs 19a (e.g., fig. 4, app. A; replacement paragraph, page 2, app. C). The framework further comprises a plurality of connecting members 20 connecting adjacent annular elements 16 from peak 19b to trough 19a (e.g., fig. 4, app. B). Each connecting member 20 has a first end and a second end, the second end is offset in a circumferential direction from the first end relative to a circumference of the body (e.g., fig. 4, app. B). Each annular element 16 has a structure, the structure of a first annular element 16a of the stent provides the stent with less compression resistance than provided by the structure of a second annular element of the stent (e.g., page 5, lines 5-8, app. A; fig. 4, app. A). The first annular element 16a is located at an end of the stent (e.g., page 5, lines 5-8, app. A; fig. 4, app. A). Each cell 24 of the stent is bounded at a first end by a portion of one annular element 16, at a second end by a portion of another annular element 16, and by two of the connecting members 20 which extend between the one annular element and the other annular element (e.g., fig. 4, app. B).

Dependent claim 28 recites the stent of claim 16, wherein the first annular element 16a spans a greater distance along the length of the stent than the second annular element 16. (e.g., fig. 4, app. B; page 5, lines 4-8, app. A).

Independent claim 17 recites a stent comprising an expandable framework defining a tubular body having a plurality of cells 24 (e.g., fig. 4, app. B; replacement paragraphs, page 3, app. B). The framework comprises a plurality of serpentine bands 16 (e.g., fig. 4, app. A; page 4, lines 1-3, app. A). Each band 16 has a proximal end and a distal end and comprises alternating peaks 19b and valleys 19a (e.g., fig. 4, app. A; replacement paragraph, page 2, app. C). The peaks 19b are located at the proximal end and the valleys are located at the distal end (e.g., fig. 4, app. A). Adjacent serpentine bands 16 are connected by connecting members 20, each connecting member 20 connected between a peak 19b and a valley 19a (e.g.,

fig. 4, app. A). Each cell 24 of the stent is defined by two of the connecting members 20 and portions of two different serpentine bands 16, one of the portions is proximal to the other portion (e.g., fig. 4, app. B). The proximal portion includes a plurality of the peaks 19b and the other portion includes a plurality of the valleys 19a (e.g., fig. 4, app. B). The peaks 19b of the proximal portion are offset circumferentially from the valleys 19a of the distal portion relative to a circumference of the body (e.g., fig. 4, app. B).

Dependent claim 20 recites the stent of claim 17, wherein the serpentine bands 16 (e.g., fig. 4, app. A) include bands of a shorter length and bands of a longer length 16a, the longer length bands located at first and second ends of the stent. *Id.*

Dependent claim 30recites the stent of claim 17, wherein each serpentine band 16 comprises peaks 19b and valleys 19a that are not connected to a connecting member 20 (e.g., fig. 4, app. B and page 5, lines 1-3, app. A).

(vi) Grounds of Rejection to be Reviewed on Appeal

Issue 1: Did the Examiner err in rejecting claims 17, 20, 29, and 30 under 35 USC § 102(e) over Pinchasik (US 5,449,373)?

Issue 2: Did the Examiner err in rejecting claims 17, 20, 29, and 30 under 35 USC § 102(b) over Palmaz (US 5,102,417)?

Issue 3: Did the Examiner err in rejecting claims 16, 25, 26, and 28 under 35 USC § 103(a) over Pinchasik in view of Kleshinski (US 5,902,317)?

Issue 4: Did the Examiner err in rejecting claims 16, 25, 26, and 28 under 35 USC § 103(a) over Palmaz (US 5,102,417) in view of Kleshinski (US 5,902,317)?

Issue 5: Did the Examiner err in rejecting claims 9, 10, 13-15, 21, 22, and 24 under 35 USC § 103(a) over Israel (US 5,733,303) in view of Pinchasik (US 5,449,372) in view of Kleshinski (US 5,902,317)?

Issue 6: Did the Examiner err in rejecting claims 18 and 19 under 35 USC § 103(a) over Palmaz (US 5,102,417) or Pinchasik (US 5,449,373) in as applied to claim 17 in further view of Lau (US 5,514,154)?

(vii) Argument

Issue 1: The Examiner erred in rejected claims 17, 20, 29, and 30 under 35 USC § 102(e) over Pinchasik (US 5,449,373).

The rejections asserted by the Examiner under 35 USC § 102(e) are *traversed* because the applied reference does not disclose a stent as recited in the rejected claims.

Independent claim 17 recites, in-part, "an expandable framework defining a tubular body having a plurality of cells, . . . each cell of the stent defined by two of the connecting members and portions of two different serpentine bands . . . ." (Emphasis added).

In rejecting claim 17, the Examiner provides the following annotated figure from Pinchasik and asserts:

> Pinchasik meets the claim language . . . . Each cell has two cross supports between a cell peak or valley and a band peak or valley. There are serpentine band peaks and valleys and there are cell peaks and valleys; see the figure below.
>
> In an alternative interpretation, it is noted that "cell" has no special definition. . . . openings in stents are called by numerous terms within the art such as cells, openings apertures [sic], holes, etc. For this reason, since cells are only exemplified as bounded by interconnecting elements, Pinchasik meets the claim language in the openings in the segments (102) are not bounded by interconnecting elements so they are not cells.

Final Office Action, pages 2-3.

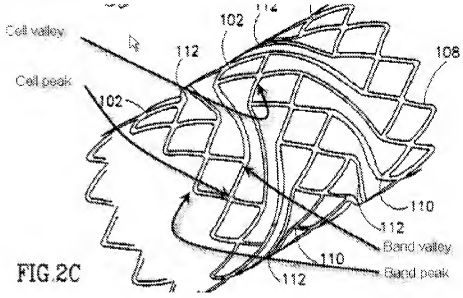


FIG.2C

Applicants disagree. As shown above in FIG. 2C, Pinchasik discloses an articulated stent "generally comprising a number of substantially rigid segments 102 connected by connectors 110." Column 3, lines 23-26. Pinchasik further states, "[s]egments 102 are preferably made up to present a fine diamond mesh of interconnected diamond shaped cells 108 having 1 mm sides on expansion as best seen in FIG. 2c." *Id* at lines 27-30 (emphasis added).

Contrary to the Examiner's assertion that the "openings in the segments (102) . . . are not cells," one of ordinary skill in the art would properly refer to these elements of Pinchasik as "cells." In this regard, Pinchasik specifically refers to "interconnected diamond shaped cells" as "cells." *E.g.*, fig. 2C and column 3, lines 27-30 of Pinchasik. However, the diamond shaped cells 108 of Pinchasik are not bounded "by two of the connecting members and portions of two different serpentine bands," as claimed.

Turning to the MPEP, section 2111.01(I) indicates that claims must be given their plain meaning consistent with the specification. Merriam-Webster's Medical Dictionary provides a plain meaning definition of a cell as "a small compartment or bounded space." http://dictionary.reference.com/browse/cell (citing Merriam-Webster's Medical Dictionary, website last visited March 30, 2010). In the context of a stent, a "cell" is an opening in the stent framework. The plain meaning of the term "cell" certainly includes the cells 108 of Pinchasik. The cells 108 of Pinchaisk, however, are not bounded by connecting members and portions of two different serpentine bands as the instant claims recite. Thus, although the cells of Pinchasik are properly referred to "cells" in a general sense, Pinchasik does not meet the particular recitations of the claim.

Moreover, the preamble of claim 17 recites, "[a] stent comprising an expandable framework defining a tubular body having a plurality of cells . . . ." Only later in the claim is it recited that "each cell of the stent defined by two of the connecting members and portions of two different serpentine bands . . . ." Consequently, although Pinchasik discloses "cells," the diamond shaped cells do not meet the specific requirements as recited in claim 17. As such, Pinchasik fails to disclose a stent as claimed.

In addition to the foregoing, the Examiner's characterization of Pinchasik has further deficiencies. Again referring to annotated figure 2C of Pinchasik, the Examiner asserts that Pinchasik has "serpentine band peaks and valleys and . . . cell peaks and valleys . . . ." Final

Office Action, page 2. Although it is unclear from the Examiner's assertion which particular structure of Pinchasik the Examiner regards as the claimed "serpentine bands," Pinchasik does not satisfy the claimed elements.

For example, if the Examiner regards the entire "rigid segments" 102 (having diamond cells) as a claimed "serpentine bands," then Pinchasik fails to disclose "serpentine bands, wherein each band . . . comprises alternating peaks and valleys . . . ." (Emphasis added). Indeed, the "band peaks" do not appear to be alternating with the "band valleys" in the Examiner's annotated figure 2C.

Alternatively, if the Examiner regards half of the "rigid segments" 102 as a claimed "serpentine bands," then Pinchasik fails to disclose "adjacent serpentine bands [which are] connected by connecting members, each connecting member connected between a peak and a valley . . . ." Halves of the rigid segment 102 appear to be directly connected without any connecting members therebetween.

For these additional reasons, Pinchasik does not disclose each and every element of claim 17. Therefore, the Examiner's rejection has failed to make out a *prima facie* case of anticipation and Applicants request that the Board reverse the Examiner's rejection of independent claim 17.

Finally, with the Examiner's assertion on page 8 that "[o]penings in stents are called by numerous terms within the art such as cells, openings, apertures, holes, etc." does not lead to the conclusion that the diamond cells of Pinchasik are not properly classified as "cells." Moreover, the fact that certain features in the art can be identified with alternative words does not mean that the diamond shaped cells of Pinchasik cannot be referred to as cells. Indeed, one of ordinary skill in the art would refer to the diamond shaped cells as "cells," at least because Pinchasik specifically refers to them as such.

Furthermore, the Examiner's assertion – that "since cells are only exemplified as bounded by interconnecting elements, Pinchasik meets the claim language in the openings in the segments (102) are not bounded by interconnecting elements so they are not cells" – must be rejected. The cells 108 of Pinchasik are still cells, in a general sense, even though they do not have the particular characteristics of the claimed cells. Consequently, the Examiner's assertion is erroneous.

For at least the foregoing reasons, Pinchasik does not disclose each and every element claimed in independent claim 17 and Applicants request that the Board reverse the Examiner's rejection thereof.

With regard to dependent claims 20, 29, and 30, these claims depend from independent claim 17 and incorporate all of the subject matter other thereof. These dependent claims are therefore patentable for at least the reasons discussed with respect to independent claim 17 and Applicants request that the Board reverse the Examiner's rejections thereof.

With further regard to dependent claim 20, it is unclear where Pinchasik discloses the additional subject matter of this claim. Claim 20 recites, "[t]he stent of claim 17 wherein the serpentine bands include bands of a shorter length and bands of a longer length, the longer length bands located at first and second ends of the stent."

In rejecting claim 20, the Examiner asserts, "[w]ith regard to claim 20, the shorter bands as claimed are those bands [of Pinchasik] between adjacent diamonds of adjacent serpentine bands." This assertion is erroneous.

As noted above, claim 20 depends from independent claim 17. Independent claim 17 recites, in-part, "wherein each band has a proximal end and a distal end and comprises alternating peaks and valleys . . . ." Thus, when the subject matter of claim 20 is properly considered in light of claim 17, it is apparent that the claimed bands of claim 20 have peaks and valleys. This structure, however, is not present Pinchasik in light of the Examiner's characterization. For this additional reason, Pinchasik is deficient and Applicants request that the Board reverse the Examiner's rejection of claim 20.

With further regard to dependent claim 30, it is unclear where Pinchasik discloses the additional subject matter of this claim. Claim 30 recites, "[t]he stent of claim 17, wherein each serpentine band comprises peaks and valleys that are not connected to a connecting member." Applicants are unable to find any reference to this claim language in the Examiner's rejection of the Final Office Action. *See e.g.*, 37 CFR 1.104(c)(2) ("The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified."). In

light of the foregoing, Applicants request that the Board reverse the Examiner's rejection of claim 30 for this additional reason.

Issue 2: The Examiner erred in rejecting claims 17, 20, 29, and 30 under 35 USC § 102(b) over Palmaz (US 5,102,417).

The rejections asserted by the Examiner under 35 USC § 102(b) are *traversed* because the applied reference does not disclose a stent as recited in the rejected claims.

Palmaz fails to disclose the subject matter of independent claim 17 for reasons similar to those discussed above with respect to Pinchasik. As shown below in figure 10 of Palmaz, Palmaz discloses "an expandable intraluminal vascular graft, or prosthesis, 70' . . . ." Column 11, lines 35-36. Palmaz further discloses that the prosthesis 70' "generally includes a plurality of prostheses, or grafts 70 . . . . Disposed between adjacent tubular members, 71, or adjacent grafts, or prostheses, 70, is at least one connector member 100 to flexibly connect adjacent tubular members 71 . . . ." *Id* at lines 48-58. The prosthesis further has slots 82. *E.g.*, column 11, line 52.

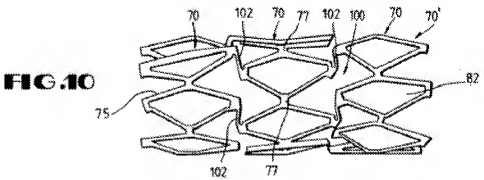


FIG.10

With reference to independent claim 17, Palmaz does not disclose a stent wherein "each cell of the stent defined by two of the connecting members and portions of two different serpentine bands," as claimed. Instead, the prosthesis of Palmaz includes diamond shaped cells 82.

Moreover, Applicants' foregoing discussion with respect to dependent claims 20 and 30 applies equally well to Palmaz. The Examiner has not identified where in Palmaz each claimed element of claims 20 and 30 are believed to be disclosed in Palmaz.

In light of the foregoing, Applicants request that the Board reverse the Examiner's rejection of claims 17, 20, 29, and 30.

Issue 3: The Examiner erred in rejecting claims 16, 25, 26, and 28 under 35 USC § 103(a) over Pinchasik in view of Kleshinski (US 5,902,317).

Independent claim 16 recites, in-part, a stent framework defining a tubular body having a plurality of cells, the framework comprising:

> a plurality of annular elements, . . . each annular element formed in a generally serpentine wave pattern having a plurality of peaks and troughs . . .
>
> each cell of the stent is bounded at a first end by a portion of one annular element, at a second end by a portion of another annular element, and by two of the connecting members which extend between the one annular element and the other annular element . . . .

The Examiner's rejection of claim 16 fails for reasons similar to those discussed above with respect to claim 17, and Kleshinski does not remedy the deficiencies of Pinchasik.

Figure 3 of Klenshinski is shown below for reference. Referring to figure 3, Kleshinski discloses "a stent includ[ing] the body portion 14 and finger portions 16 extending generally axially from one, or both, ends of the body portion. The fingers facilitate a gradual reduction in radially outwardly extending pressure exerted by the stent on the wall of a vascular passageway . . . ." Column 4, lines 3-6.

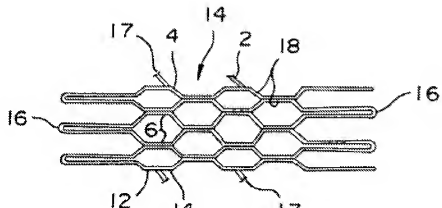


FIG. 3

Despite the disclosure of Kleshinski, however, neither Pinchasik nor Kleshinski, whether considered independently or in combination, discloses, teaches, suggests, or otherwise renders obvious a stent wherein each cell is "bounded at a first end by a portion of one annular element, at a second end by a portion of another annular element, and by two of the connecting members which extend between the one annular element and the other annular element." Consequently, Applicants request that the Board reverse the Examiner's rejection of independent claim 16 and dependent claims 25, 26, and 28, which depend therefrom.

In addition, with respect to claim 28, neither Pinchasik nor Kleshinski, whether considered independently or in combination, discloses, teaches, suggests, or otherwise renders obvious a stent "wherein each annular element comprises peaks and troughs that are not connected to a connecting member," as is claimed in dependent claim 28. Moreover, Applicants are unable to find any substantive rejection of this claim in the Final Office Action. *See* MPEP § 2142 ("[t]he Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit."). Therefore, Applicants request that the Board reverse the Examiner's rejection of dependent 28 for these additional reasons.

Issue 4: The Examiner erred in rejecting claims 16, 25, 26, and 28 under 35 USC § 103(a) over Palmaz (US 5,102,417) in view of Kleshinski (US 5,902,317).

The Examiner's rejection of claims 16, 25, 26, and 28 over Palmaz in view of Kleshinski is *traversed*. The rejection of claim 16 is traversed for essentially the same reasons as discussed above with respect to Pinchasik. In particular, Palmaz does not disclose a stent wherein each cell is "bounded at a first end by a portion of one annular element, at a second end by a portion of another annular element, and by two of the connecting members which extend between the one annular element and the other annular element," as claimed in independent claim 16. Instead, the prosthesis of Palmaz includes diamond shaped cells 82. Moreover, even when considered in light of Kleshinski, Palmaz fails to render obvious Applicants' claim 16. The stent of Kleshinski does not contemplate a stent with each cell having the claimed structure. Consequently, Applicants request that the Board reverse the Examiner's rejection of independent claim 16 and dependent claims 25, 26, and 28.

With further regard to dependent claim 28, Applicants are again unable to find any substantive discussion of this claim in the Final Rejection. As discussed above with respect to the rejection of claim 28 over Pinchasik and Kleshinski, the Examiner has failed to comply with the requirements set forth in *KSR* – the rejection has not been made explicit. Therefore, Applicants request that the Board reverse the Examiner's rejection of dependent claim 28 for this additional reason.

Issue 5: The Examiner erred in rejecting claims 9, 10, 13-15, 21, 22, and 24 under 35 USC § 103(a) over Israel (US 5,733,303) in view of Pinchasik (US 5,449,372) in view of Kleshinski (US 5,902,317).

The rejection of independent claim 9 and dependent claims 10, 13-15, 21, 22, and 24 over Israel, Pinchasik, and Kleshinski is *traversed*.

As shown below in figure 1 of Israel, Israel discloses a stent 30. Column 2, line 52. The stent 30 of Israel has "two meander patterns [which] are labeled 11 and 12 . . . ." *Id* at lines 61-62.

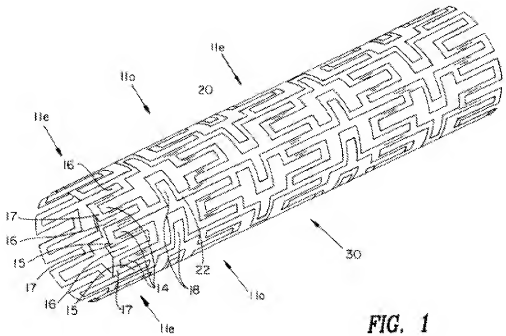


FIG. 1

In rejecting independent claim 9 over Israel, Pinchasik, and Kleshinski, the Examiner proposes modifying the stent of Israel by offsetting the cells/bands from one another and using circumferentially offset/helical connectors as taught by Pinchasik. Specifically, the Examiner states that "it would have been obvious to circumferentially offset the cell ends of Israel for the same reasons that Pinchasik does the same or in order to provide better coverage between stent segments." Final Office Action, page 6. Applicants disagree.

One of ordinary skill in the art would not have been motivated to use a connector configuration as taught by Pinshasik with the stent of Israel because Israel specifically teaches away from the use of helical connectors. The Background section of Israel discusses the Palmaz patent (US 5,102,417) and notes that the Palmaz stent includes helical connectors. Israel at column 1, lines 33-44. In particular, Israel warns that "helical connectors twist," further stating, "[t]he twisting motion is most probably harmful to the blood vessel." *Id* at lines 41-43. As shown in figures 2 and 4 of Israel, below, Israel instead teaches a "[m]eander pattern 12 [that] is an horizontal pattern having an horizontal center line 13." Column 3, lines 3-4.

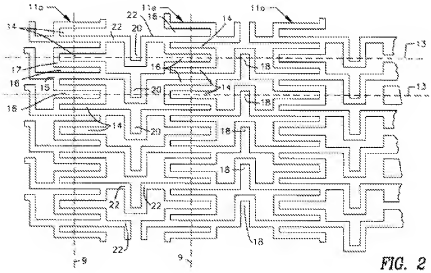


FIG. 2

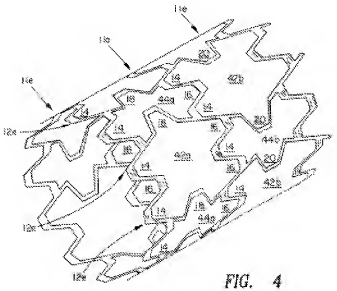
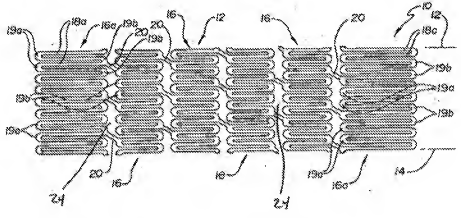


FIG. 4

In light of the Background section of Israel, discussing the purported disadvantages of the helical connectors of the stent of Palmaz, one of ordinary skill in the art would not be motivated to incorporate the connectors of Pinchasik therein. Pinchasik teaches a stent having helical connectors similar to those of Palmaz. However, the helical connectors of Pinchasik are longer than those of Palmaz, and are therefore even more susceptible to "twisting motion." Thus, one of ordinary skill in the art would not be motivated to use the helical connectors of Pinchasik with the stent of Israel. Consequently, the Examiner's proposed modification would not be carried out.

In addition to the foregoing, the Examiner proposes modifying the Israel/Pinchasik stent with the "fingers" of Kleshinski. Final Office Action, page 6. Even if this modification were made, however, the resulting stent still would not satisfy the claimed elements. For example, claim 9 recites, in-part, "the valley portions of the first annular element having the same shape as the peak portions of the first annular element . . . ." *See e.g.*, figure 4 of the immediate application, below.

Fig. 4



Even if the Israel/Pinchasik stent were modified with the "fingers" of Kleshinski as proposed by the Examiner, the resulting device would not meet Applicants' claim recitation. Such a modification would change one end of the segment but not the other. FIG. 1 of Kleshinshi is provided below for reference.

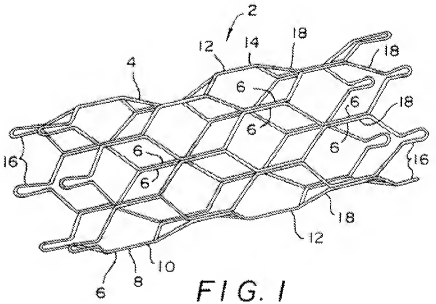


FIG. 1

To the extent the segment of the Israel/Pinchasik device has valley portions and peaks portions, the resulting segment (as modified by Kleshinski) would have "valley portions" of a different shape than the "peak portions." This would be the case because the "fingers" 16 would be added to only one end of the segment.

In addition, Applicants disagree with the Examiner's assertion on page 6 of the Office Action – that "[t]he fingers have the same shape as the valley portions when the stent is compressed; see Figure 5 of Kleshinski.". FIG. 5 of Kleshinski is shown below for reference.

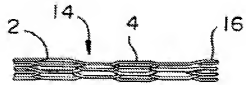


FIG. 5

Kleshinski describes FIG. 5 as "a side elevational view of the stent shown in FIG. 1, but shown in a compressed condition." Column 3, lines 16-17. It is unclear from the limited view of FIG. 5 what the particular shape of fingers 16 is. However, it is still evident that that the shape of the fingers is different from the shape of the cells 18. In particular, it is noted that the skeletal frame 2 of Kleshinski is preferably formed of a single wire 4. Column 3, line 50. "The wire 4 includes a plurality of abutting straight portions 6 which are joined to each other . . . ." *Id*

at column 4, lines 50-51. Thus, the straight portions abut one another along either length. *E.g.*, FIG. 1. In contrast, the structure of the fingers 16 appears to be formed in a looping fashion at the end of the finger. This structural difference between the arrangement of the fingers and the straight portions leads to the conclusion that the fingers have a different shape than the cells of Kleshinski. Consequently, the Examiner's assertion that "[t]he fingers have the same shape as the valley portions when the stent is compressed," is erroneous and the Examiner's proposed device does not render obvious the stent of claim 9.

For at least the foregoing reasons, Applicants request that the Board reverse the Examiner's rejection of independent claim 9 and dependent claims 10, 13-15, 21, 22, and 24, which depend therefrom.

Issue 6: The Examiner erred in rejecting claims 18 and 19 under 35 USC § 103(a) over Palmaz (US 5,102,417) or Pinchasik (US 5,449,373) in as applied to claim 17 in further view of Lau (US 5,514,154).

The rejection of dependent claims 18 and 19 over Palmaz or Pinchasik in view of Lau is *traversed*. It is unclear how the addition of Lau would remedy the deficiencies of Palmaz or Pinchasik, respectively, discussed above with respect to independent claim 17. Consequently, the Examiner has failed to establish a *prima facie* case of obviousness and Applicants request that the Board reverse the Examiner's rejection of dependent claims 18 and 19.

Conclusion

Based on at least the foregoing arguments, Applicants respectfully submit that the rejections presented by the Examiner fail to anticipate or render obvious Applicants' claims. Accordingly, Applicants respectfully request that the Board reverse the Examiner's rejections

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

Date: March 31, 2010

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(viii) Claims Appendix

Claim 9. A stent having a plurality of cells and a plurality of segments which form a tubular body, the body having a circumference and comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, each annular element formed in a generally serpentine wave pattern and containing alternating valley portions and peak portions,

a plurality of connecting members connecting adjacent annular elements to form a plurality of cells which are bounded at a first end by a portion of one annular element, at a second end by a portion of another annular element and two connecting members which extend between the one annular element and the other annular element, the first end offset in a circumferential direction from the second end relative to the circumference of the body,

each annular element having a structure, the structure of a first annular element of the stent providing the stent with less compression resistance than provided by the structure of a second annular element of the stent, the valley portions of the first annular element having the same shape as the peak portions of the first annular element, wherein the first annular element is located at an end of the stent, and

wherein each cell of the stent is bounded at a first end by a portion of one annular element, at a second end by a portion of another annular element, and by two connecting members which extend between the one annular element and the other annular element.

Claim 10. The stent of claim 9, wherein the connecting members are connected to the peak portions and valley portions of the adjacent annular elements.

Claim 13. The stent of claim 9, wherein the first and second annular elements are spaced apart longitudinally along the stent.

Claim 14. The stent of claim 9 wherein the annular elements and connecting members are made of Nitinol.

Claim 15. The stent of claim 9 wherein the annular elements and connecting members are made of a shape memory alloy.

Claim 16. A stent comprising an expandable framework defining a tubular body having a plurality of cells, the framework comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, each annular element formed in a generally serpentine wave pattern having a plurality of peaks and troughs,

a plurality of connecting members connecting adjacent annular elements from peak to trough; each connecting member having a first end and a second end, the second end offset in a circumferential direction from the first end relative to a circumference of the body,

each annular element having a structure, the structure of a first annular element of the stent providing the stent with less compression resistance than provided by the structure of a second annular element of the stent, wherein the first annular element is located at an end of the stent, and

wherein each cell of the stent is bounded at a first end by a portion of one annular element, at a second end by a portion of another annular element, and by two of the connecting members which extend between the one annular element and the other annular element.

Claim 17. A stent comprising an expandable framework defining a tubular body having a plurality of cells, the framework comprising:

a plurality of serpentine bands, wherein each band has a proximal end and a distal end and comprises alternating peaks and valleys, the peaks located at the proximal end and the valleys located at the distal end; adjacent serpentine bands connected by connecting members, each connecting member connected between a peak and a valley, each cell of the stent defined by two of the connecting members and portions of two different serpentine bands, one of the portions being proximal to the other portion, the proximal portion including a plurality of said peaks, the other portion including a plurality of said valleys, the peaks of the proximal portion being offset circumferentially from the valleys of the distal portion relative to a circumference of the body.

Claim 18. The stent of claim 17 wherein the stent is made from Nitinol.

Claim 19. The stent of claim 17 wherein the stent is made of a self-expandable material.

Claim 20. The stent of claim 17 wherein the serpentine bands include bands of a shorter length and bands of a longer length, the longer length bands located at first and second ends of the stent.

Claim 21. The stent of claim 9, wherein the first annular element spans a greater distance along the length of the stent than the second annular element.

Claim 22. The stent of claim 9, wherein the connecting members are non-parallel to a stent longitudinal axis.

Claim 24. The stent of claim 9, wherein each annular element comprises peaks and valleys that are not connected to a connecting member.

Claim 25. The stent of claim 16, wherein the first and second annular elements are spaced apart longitudinally along the stent

Claim 26. The stent of claim 16, wherein the first annular element spans a greater distance along the length of the stent than the second annular element

Claim 28. The stent of claim 16, wherein each annular element comprises peaks and troughs that are not connected to a connecting member.

Claim 29. The stent of claim 17, wherein the connecting members are non-parallel to a stent longitudinal axis.

Claim 30. The stent of claim 17, wherein each serpentine band comprises peaks and valleys that are not connected to a connecting member.

(ix) Evidence Appendix

In addition to Appendices A-C, discussed above in the Summary of Claimed Subject Matter section of this Brief, Appendix D is also included herewith. These Appendices are included for the purpose of providing a Specification in its current form.

Included in Appendix D is a copy of the Preliminary Amendment filed concurrently with the Application on August 21, 2001, wherein the Abstract and priority data were updated and new claims were presented.

(x) Related Proceedings Appendix

Decision from BPAI for Application No. 08/511,076 mailed on Sept. 25, 2001

RELATED PROCEEDINGS APPENDIX

Decision from BPAI for App. No. 08/511,076 mailed on September 25, 2001

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BRIAN J. BROWN and MICHAEL L. DAVIS

Appeal No. 1998-0022
Application No. 08/511,076

ON BRIEF

Before CALVERT, ABRAMS, and BAHR, Administrative Patent Judges.

ABRAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-10, which are all of the claims pending in this application.

We AFFIRM.

BACKGROUND

The appellants' invention relates to a stent for implantation within a body vessel. An understanding of the invention can be derived from a reading of exemplary claim 10, which appears in the appendix to the Brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Palmaz	5,102,417	Apr. 7, 1992
Lau et al. (Lau) (European Patent Application)	540,290	May 5, 1993

Claims 1-7, 9 and 10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lau.

Claims 1-7, 8, 9 and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Lau in view of Palmaz.[1]

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the Answer (Paper No. 11) for the examiner's complete reasoning in support of the rejections, and to the Brief (Paper No. 10) for the appellants' arguments thereagainst.

---

[1]In both the final rejection and the Answer, the rejection of claim 8 was separately recited as "Lau et al and Palmaz as applied to claims 1-7 and 9-10 above, and further in view of Lau et al (EP 0540290)." However, only one Lau reference has been listed by the examiner, and it is EP 0540290.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

The Rejection Under Section 102

At the outset, we note with regard to the anticipation rejection that the appellants have chosen to group together claims 1-7, 9 and 10 (Brief, page 7). Therefore, these claims will stand or fall with representative claim 10. See 37 CFR 1.192(c)(7) and Section 1206 of the Manual of Patent Examining Procedure.

Anticipation under Section 102 is established only when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of the claimed invention. See In re Paulsen, 30 F.3d 1475, 1480-1481, 31 USPQ2d 1671, 1675 (Fed. Cir. 1994) and In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). Anticipation by a prior art reference does not require either the inventive concept of the claimed subject matter or recognition of inherent properties that may be possessed by the reference. See Verdegaal Brothers Inc. v. Union Oil Co. of California, 814 F.2d 628, 633, 2 USPQ2d 1051, 1054 (Fed. Cir. 1987). It does not require that the reference teach what the applicant is claiming, but only that the claim on appeal "read on" something disclosed in the reference, that is, all

limitations of the claim are found in the reference. See Kalman v. Kimberly-Clark Corp, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert denied, 465 U.S. 1026 (1984).

It is the examiner's position that all of the subject matter recited in claim 10 is disclosed or taught by Lau. The only argument offered by the appellants in rebuttal to this conclusion is that their claims require that the angular interconnecting elements which connect together adjacent segments of the stent "are not parallel to the longitudinal axis of the stent," a condition which they urge is not met by the embodiment shown in Figure 11 of Lau, in which the interconnecting elements are parallel to the longitudinal axis of the stent (Brief, pages 7 and 8).

Claim 10 recites a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body with

> each segment being defined by a member formed in an undulating pattern of interconnected paired struts . . . in which adjacent pairs of struts in a given segment are interconnected at only one end in an alternating arrangement, the interconnected ends of each pair in each segment alternating between ends of pairs and the interconnected ends of the strut pairs of one segment being positioned substantially opposite to the interconnected ends of an adjacent segment (emphasis added).

The claim goes on to recite "a plurality of interconnecting elements each extending angularly from one segment to an adjacent segment" (emphasis added). From our perspective, since each segment is defined in claim 10 as a member including a portion which interconnects the ends of adjacent struts, an interconnecting element that

angularly extends from "a segment" to "an adjacent segment" meets the literal language of the claim if it extends at an angle from any portion of the first segment. Our position is best explained by relating this to the embodiment shown in Figure 11 of Lau. It is our view that Lau's elements 13, which interconnect adjacent segments of the stent, are "extending angularly from one segment to an adjacent segment" (emphasis added), as recited in the claim, in that they are at an angle (90 degrees) to the U-shaped portions of each segment that connects the ends of adjacent struts. It is true that elements 13 are oriented parallel to the longitudinal axis of the Lau stent, however, the fact is that claim 10 is devoid of language which would limit "angularly" to mean that the angle is measured with respect to the longitudinal axis of the stent, or would require it to be so interpreted.

It therefore is our conclusion that all of the language in representative claim 10 reads on the stent disclosed in Lau's Figure 11, and thus the reference anticipates the claim. We are not persuaded otherwise by the appellants' argument, which simply is not commensurate with the scope of the language in the representative claim.

The rejection of representative claim 10 and claims 1-7 and 9, which have been grouped therewith, as being anticipated by Lau is sustained.

The Rejections Under Section 103

Claims 1-7, 9 and 10 also stand rejected as being unpatentable over Lau in view of Palmaz. Again, the appellants have chosen to group these claims together and, as

before, we have selected claim 10 to be the representative claim. As far as this rejection is concerned, we determined above that claim 10 is anticipated by Lau and, since anticipation is the epitome of obviousness,[2] we also will sustain the Section 103 rejection of claims 1-7, 9 and 10.

The same reasoning applies to claim 8, the separate patentability of which was not argued in the Brief (page 11), and we also will sustain the Section 103 rejection of this claim.

CONCLUSION

All of the rejections are sustained.

The decision of the examiner is affirmed.

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[2]In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

IAN A. CALVERT
Administrative Patent Judge

NEAL E. ABRAMS
Administrative Patent Judge

JENNIFER D. BAHR
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS
) AND
) INTERFERENCES

NEA:pgg

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA , MN 55343-9185

EVIDENCE APPENDIX

A. Application as-filed

Fig. 1

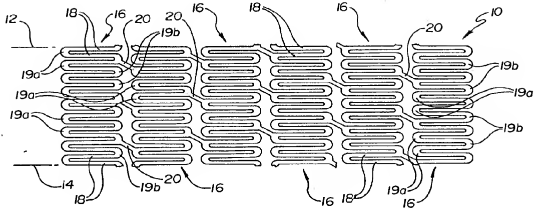

12
18
16
20
20
19b
16
18
16
10
20
19a
19b
19a
19a
19a
19b
14
18
19b
20
16
16
18
19a
16

Fig. 4

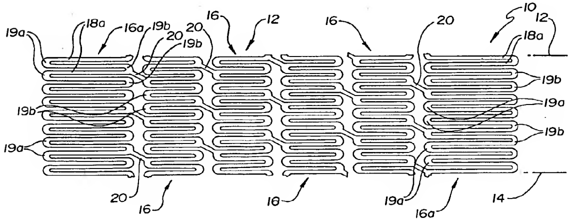

19a
18a
16a
19b
20
20
19b
16
12
16
20
10
12
18a
19b
19b
19a
19b
19a
20
16
16
19a
16a
14

Fig. 2

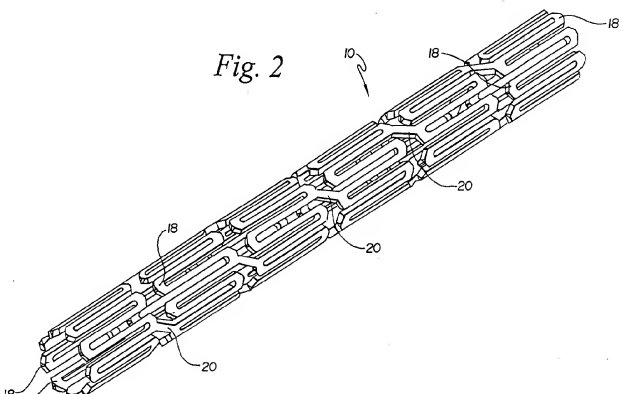
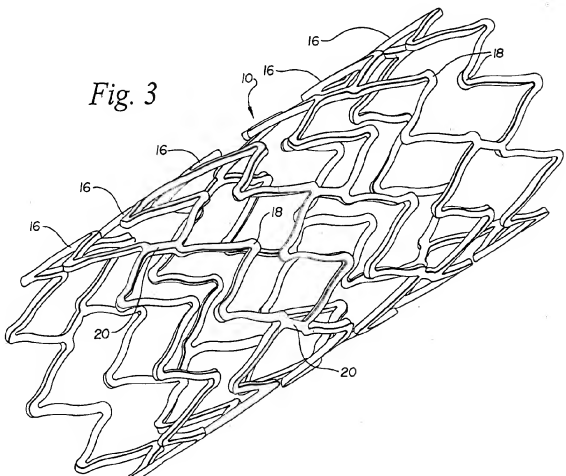


Fig. 3



IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

This application is a Continuation of application Serial No. 08/396,569, filed March 1, 1995, the disclosure of which is hereby incorporated by reference.

Field of the Invention

This invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel. More specifically, it relates to a tubular expandable stent of improved longitudinal flexibility.

Background of the Invention

Stents are placed or implanted within a blood vessel for treating stenoses, strictures or aneurysms therein. They are implanted to reinforce collapsing, partially occluded, weakened, or dilated sections of a blood vessel. They have also been implanted in the urinary tract and in bile ducts.

Typically, a stent will have an unexpanded (closed) diameter for placement and an expanded (opened) diameter after placement in the vessel or the duct. Some stents are self-expanding and some are expanded mechanically with radial outward force from within the stent, as by inflation of a balloon.

An example of the latter type is shown in U.S. Patent No. 4,733,665 to Palmaz, which issued March 29, 1988, and discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes an arrangement wherein a balloon inside the stent is inflated to expand the stent by plastically deforming it, after positioning it within a blood vessel.

A type of self-expanding stent is described in U.S. Patent No. 4,503,569 to Dotter which issued March 12, 1985, and discloses a shape memory stent which expands to an implanted configuration with a change in temperature. Other types of self-expanding stents not made of shape memory material are also known.

This invention is directed to stents of all these types when configured so as to be longitudinally flexible as described in detail hereinbelow. Flexibility is a desirable feature in a stent so as to conform to bends in a vessel. Such stents are known in the prior art. Examples are shown in U.S. Patent No. 4,856,516 to

Hillstead; U.S. Patent No. 5,104,404 to Wolff; U.S. Patent No. 4,994,071 to MacGregor; U.S. Patent No. 5,102,417 to Palmaz; U.S. Patent No. 5,195,984 to Schatz; U.S. Patent No. 5,135,536 to Hillstead; U.S. Patent 5,354,309 to Shepp-Pesch et al.; EPO Patent Application 0 540 290 A2 to Lau; EPO Patent Application No. 0 364 787 B1 to Schatz, and PCT Application WO 94/17754 (also identified as German Patent Application 43 03 181).

Generally speaking, these kinds of stents are articulated and are usually formed of a plurality of aligned, expandable, relatively inflexible, circular segments which are interconnected by flexible elements to form a generally tubular body which is capable of a degree of articulation or bending. Unfortunately, a problem with such stents is that binding, overlapping or interference can occur between adjacent segments on the inside of a bend due to the segments moving toward each other and into contact or on the outside of a bend the segments can move away from each other, leaving large gaps. This can lead to improper vessel support, vessel trauma, flow disturbance, kinking, balloon burst during expansion, and difficult recross for devices to be installed through already implanted devices and to unsupported regions of vessel.

A diamond configuration with diagonal connections between each and every diamond of each segment is also known but such closed configurations lack flexibility.

It is an object of this invention to provide a longitudinally flexible stent of open configuration that avoids these problems and exhibits improved flexibility (radially and longitudinally) in the stent body segments thereof rather than in flexible joints between the segments.

Summary of the Invention

To this end, the invention provides a tubular expandable stent, comprising: a plurality of cylindrical shaped open cylindrical segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating flexible pattern of interconnected substantially parallel struts with pairs thereof having alternating interconnecting end portions to define the periphery of the expandable stent segment, and in which the connected end portions of paired struts in each segment, before the

stent is expanded, are positioned substantially opposite to connected end portions of paired struts in adjacent segments. The segments are interconnected by a plurality of interconnecting elements extending from some of the connected end portions on one segment to some of the connected end portions on adjacent segments in such a manner that there are three or more legs between points of connection from one side of each segment to its other side. Additionally, the connecting elements extend angularly from connecting end portion of one segment to connecting end portion of an adjacent segment, not to an opposite connecting end portion on an adjacent segment, whereby upon expansion of the stent the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate flexing of the stent within paired struts without interference between adjacent segments, rather than by means of articulating flexible connectors between segments. As a result, the connectors between the segments are not intended to flex or bend under normal use.

Brief Description of the Figures

Figure 1 shows a flat view of an unexpanded stent configuration according to the invention.

Figure 2 shows the pattern of Figure 1 in a tubular, unexpanded stent.

Figure 3 shows an expanded stent of the configuration shown in Figure 1.

Figure 4 shows a flat view of an alternate unexpanded stent configuration according to the invention.

Best Mode Description of the Invention

Turning to the Figures, Figure 1 and Figure 2 show a fragmentary flat view of an unexpanded stent configuration and the actual tubular stent (unexpanded), respectively. That is, the stent is shown for clarity in Figure 1 in the flat and may be made from a flat pattern 10 (Figure 1) which is formed into a tubular shape by rolling the pattern so as to bring edges 12 and 14 together (Figure 1). The edges may then joined as by welding or the like to provide a configuration such as that shown in Figure 2.

The configuration can be seen in these Figures to be made up of a plurality of adjacent segments generally indicated at 16, each of which is formed in an undulating flexible pattern of substantially parallel struts 18. Pairs of struts are interconnected at alternating end portions 19a and 19b. As is seen in Figure 1, the interconnecting end portions 19b of one segment are positioned opposite interconnecting end portions 19a of adjacent segments. The end portions as shown are generally elliptical but may be rounded or square or pointed or the like. Any configuration of end portions is acceptable so long as it provides an undulating pattern, as shown. When the flat form 10 is formed into an unexpanded tube as shown in Figure 2, the segments are cylindrical but the end portions 19 of adjacent segments remain in an opposed position relative to each other.

A more preferred method of manufacture begins with a thin walled tube which is then laser cut to provide the desired configuration. It may also be chemically etched or EDM'd (electrical discharge machined) to form an appropriate configuration.

Interconnecting elements 20 extend from one end portion 19 of one segment 16 to another end portion 19 of another adjacent segment 16 but not to an oppositely positioned end portion 19 of an adjacent segment 16. There are at least three struts included between the points on each side of a segment 16 at which an interconnecting element 20 contacts an end portion 19. This results in the interconnecting elements 20 extending in an angular direction between segments around the periphery of the tubular stent. Interconnecting elements 20 are preferably of the same length but may vary from one segment to the other. Also, the diagonal direction may reverse from one segment to another extending upwardly in one case and downwardly in another, although all connecting elements between any pair of segments are substantially parallel. Figure 1, for example shows them extending downwardly, right to left. Upwardly would extend up left to right in this configuration.

As a result of this angular extension of the interconnecting elements 20 between adjacent segments and loops, upon expansion of the stent as seen in Figure 3, the closest adjacent end portions 19 between segments 16 are displaced from each other and are no longer opposite each other so as to minimize the possibility of binding or overlapping between segments, i.e., pinching.

The number of interconnecting elements 20 may vary depending on circumstances in any particular instance. Three per segment are satisfactory for the configuration shown and at least three will be used typically.

The alternate design shown in Figure 4 includes longer struts 18a in the two end segments 16a than in the intermediate segments 16. This allows the end segments (16a) to have less compression resistance than the intermediate segments (16), providing a more gradual transition from the native vessel to the support structure of the stent. Otherwise, the configuration is the same as that shown in Figure 1.

As already indicated, this invention is applicable to self-expanding configurations, mechanically expandable configurations and to a wide variety of materials, including both metal and plastic and any other material capable of functioning as an expandable stent. For example, the stent may be of metal wire or ribbon such as tantalum, stainless steel or the like. It may be thin-walled. It may be of shape memory alloy such as Nitinol or the like, etc.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

1. A tubular, flexible, expandable stent, comprising:

a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating pattern of interconnected substantially parallel struts to define the periphery of the expandable stent body, and in which adjacent pairs of struts in a given segment are interconnected at opposite ends, interconnected ends of one segment being positioned substantially opposite to interconnected ends of an adjacent segment, and

a plurality of interconnecting elements each extending from an end of paired struts on one segment to an end of paired struts on an adjacent segment, the elements extending angularly from one end on one segment to another end, not to an opposite end, on an adjacent segment, the distribution of the elements being such that there are at least three struts between each connecting point on opposite sides of the segments,

whereby, upon expansion of the stent, the paired struts of the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments and without interference between adjacent segments.

2. The stent of claim 1 wherein the material of which it is comprised is metal.

3. The stent of claim 2 wherein the metal is a shape memory alloy.

4. The stent of claim 2 wherein the stent is a thin-walled tubular member.

5. The stent of claim 1 in a self-expanding configuration.

6. The stent of claim 1 in a mechanically expandable configuration.

7. The stent of claim 1 wherein the interconnecting elements between adjacent segments are of the same length.

8. The stent of claim 1 wherein the stent includes end segments and intermediate segments and the end segments of the stent include longer struts than the intermediate segments of the stent.

add a2

Abstract of the Disclosure

IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

Segmented articulatable stent of open structure comprised of end-connected struts making up the segments with angular interconnects between segments.

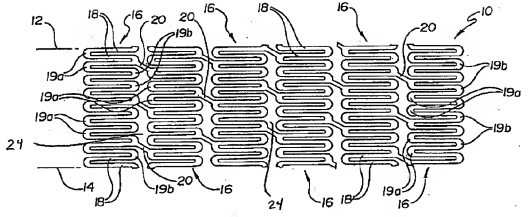
B. Amended Drawings and Specification as filed on May 20, 2003

In the Figures:

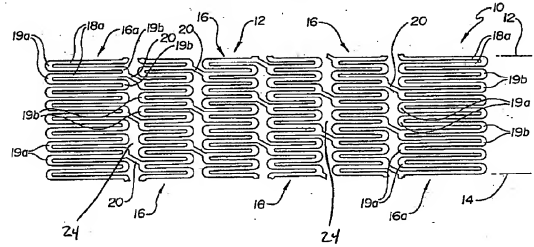
Applicants submit proposed amendments to Figs. 1, 3 and 4 for the Examiner's approval. Proposed amendments are shown in red. Specifically, reference numeral 24 had been added to each of the Proposed Figures in two locations. No new matter has been added.

O.K. to make changes
08/04/03

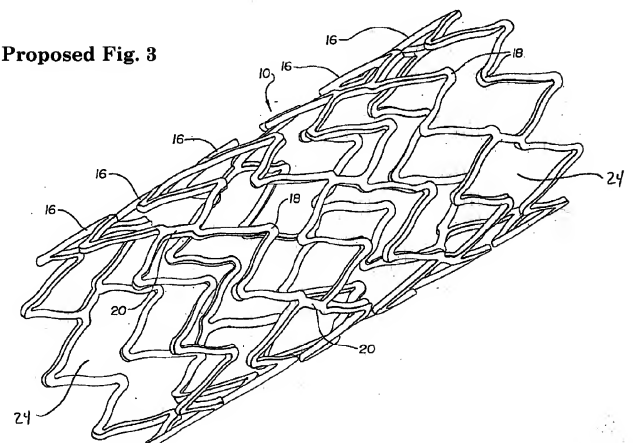
Proposed Fig. 1



Proposed Fig. 4



Proposed Fig. 3



In The Specification:

Please replace the paragraph beginning at page 4, line 16 with the following amended paragraph:

Interconnecting elements 20 extend from one end portion 19 of one segment 16 to another end portion 19 of another adjacent segment 16 but not to an oppositely positioned end portion 19 of an adjacent segment 16. Interconnecting elements 20 and adjacent segments 16 form a plurality of cells 24 that change shape upon expansion of the stent. There are at least three struts included between the points on each side of a segment 16 at which an interconnecting element 20 contacts an end portion 19. This results in the interconnecting elements 20 extending in an angular direction between segments around the periphery of the tubular stent. Interconnecting elements 20 are preferably of the same length but may vary from one segment to the other. Also, the diagonal direction may reverse from one segment to another extending upwardly in one case and downwardly in another, although all connecting elements between any pair of segments are substantially parallel. Figure 1, for example shows them extending downwardly, right to left. Upwardly would extend up left to right in this configuration.

Please replace the paragraph beginning at page 5, line 4 with the following amended paragraph:

The alternate design shown in Figure 4 includes longer struts 18a in the two end segments 16a than in the intermediate segments 16. This allows the end segments (16a) to have less compression resistance than the intermediate segments (16), providing a more gradual transition from the native vessel to the support structure of the stent. The shape of cells 24 near the end of the stent is also modified. Otherwise, the configuration is the same as that shown in Figure 1.

C. Amended Specification as filed on September 5, 2006

Amendments To The Specification:

Please replace the paragraph starting on line 1 of page 4 with the following replacement paragraph:

The configuration can be seen in these Figures to be made up of a plurality of adjacent segments generally indicated at 16, each of which is formed in an undulating flexible pattern of substantially parallel struts 18. Pairs of struts are interconnected at alternating end portions 19a and 19b. As is seen in Figure 1, the interconnecting end portions, or peaks 19b of one segment are positioned opposite interconnecting end portions, valleys, or troughs 19a of adjacent segments. The end portions as shown are generally elliptical but may be rounded or square or pointed or the like. Any configuration of end portions is acceptable so long as it provides an undulating pattern, as shown. When the flat form 10 is formed into an unexpanded tube as shown in Figure 2, the segments are cylindrical but the end portions 19 of adjacent segments remain in an opposed position relative to each other.

D. Preliminary Amendment as filed on August 21, 2001

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Brown et al.
Application No.:	Not yet assigned
Filed:	Concurrently herewith
For:	Improved Longitudinally Flexible Expandable Stent
Examiner:	Not yet assigned
Group Art Unit:	Not yet assigned

Box Patent Application
Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-10079

PRELIMINARY AMENDMENT

Before beginning examination and calculating the fees in this application, please amend the above-identified application as indicated below:

In the Specification

Please amend the specification on page 1, by replacing the paragraph starting on line 3 with the following paragraph:

--This application is a Continuation application from US Application No. 08/511,076 filed August 3, 1995 which is a continuation in part from US Application No. 08/396,569 filed March 1, 1995, the contents of both of which are hereby incorporated by reference --

In the Claims

Please cancel claims 1-8 without prejudice or disclaimer and add claims 9-14 as follows:

--9.(New) A stent having a plurality of segments and comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state;

at least one connecting member connecting adjacent annular elements to form a plurality of cells, each cell having an area;

the stent having a first segment and a second segment, with the first segment having a plurality of combined adjacent cells that impart greater flexibility to the first segment than the second segment.

10.(New) The stent of claim 9, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration, and wherein the connecting members are connected to the apices of the adjacent annular members.

11.(New) The stent of claim 9, wherein the difference in flexibility between the first and second segments is a difference in the longitudinal flexibilities in the first and second segments.

12.(New) The stent of claim 9, wherein the difference in flexibility between the first and second segments is a difference in the radial flexibilities in the first and second segments.

13.(New) The stent of claim 9, wherein the first and second segments are spaced apart longitudinally along the stent.

14.(New) The stent of claim 9 wherein the annular elements and connecting members are made of Nitinol.

15.(New) The stent of claim 9 wherein the annular elements and connecting members are made of a shape memory alloy.--

In the Abstract

On page 7, please replace the abstract, beginning on line 5, with the following abstract:

--A stent is provided with a plurality of annular elements. Each annular element has a compressed state and an expanded state. At least one connecting member connects adjacent annular elements to form a plurality of cells with each cell having an area. The stent has a first segment and a second segment, with the first segment having a plurality of combined adjacent cells that impart greater flexibility to the first segment than the second segment.--

REMARKS

This application is a continuation of US Application No. 08/511,076 filed August 3, 1995 which is a continuation in part from US Application No. 08/396,569 filed March 1, 1995. The specification has been amended to reflect this chain of continuity.

Claims 1-8 have been canceled from the application without prejudice or disclaimer in order to prosecute new claims 9-14. Support for new claims 9-13 is found in Fig. 4 and page 5, lines 4-9 of the application as filed and in the parent application, US Application No. 08/511,076. Support for claims 14 and 15 is found on page 5, line 15 of the application as filed and of the parent application, US Application No. 08/511,076. No new matter has been added.

In accordance with 37 CFR 1.607(c), Applicant notes that many of the above claims correspond substantially to claims from US 6,106,548 to Roubin et. al. (Roubin), issued August 22, 2000. The claims are not identical, however, in that the "wherein" clause of claim 1 of Roubin has been omitted in claim 9 of the instant application.

A table indicating the correspondence is provided below.

Claim in instant application	Claim in Roubin
9	1;
10	2;
11	5;
12	6;
13	7;
14	1; and
15	1.

Applicant notes, however, that the correspondence identified above is not intended to constitute a statement that the scope of the claims is identical.

Respectfully submitted,

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The application has been amended on page 1 by replacing the paragraph beginning on line 3 as follows:

[This application is a Continuation application of application Serial No. 08/396,569, filed March 1, 1995, the disclosure of which is hereby incorporated by reference.] This application is a Continuation application from US Application No. 08/511,076 filed August 3, 1995 which is a continuation in part from US Application No. 08/396,569 filed March 1, 1995, the contents of both of which are hereby incorporated by reference.

On page 7, the abstract, beginning on line 5, has been amended as follows:

[Segmented articulatable stent of open structure comprised of end-connected struts making up the segments with angular interconnects between segments.]A stent is provided with a plurality of annular elements. Each annular element has a compressed state and an expanded state. At least one connecting member connects adjacent annular elements to form a plurality of cells with each cell having an area. The stent has a first segment and a second segment, with the first segment having a plurality of combined adjacent cells that impart greater flexibility to the first segment than the second segment.

Claims 1-8 have been canceled and new claims 9-15 added to the application.